

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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RECEIVED MSJ 19 MAR 2004 SUB	
Diary <input checked="" type="checkbox"/>	Date of mailing (day/month/year)

PCT
WRITTEN OPINION
(PCT Rule 66)

Applicant's or agent's file reference
0351011936

Date of mailing
(day/month/year) **17 MAR 2004**

REPLY DUE within **TWO MONTHS**
from the above date of mailing

International Application No.
PCT/AU2003/000998

International Filing Date (day/month/year)
7 August 2003

Priority Date (day/month/year)
9 August 2002

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. ⁷ A61K 47/22, 31/355, 31/565, 31/568, A61P 5/24, 15/00

Applicant
VITAL HEALTH SCIENCES PTY LTD et al

1. This written opinion is the **first** drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:

I	<input checked="" type="checkbox"/>	Basis of the opinion
II	<input type="checkbox"/>	Priority
III	<input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/>	Lack of unity of invention
V	<input checked="" type="checkbox"/>	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input checked="" type="checkbox"/>	Certain documents cited
VII	<input type="checkbox"/>	Certain defects in the international application
VIII	<input checked="" type="checkbox"/>	Certain observations on the international application
3. The **FINAL DATE** by which the international preliminary examination report must be established according to Rule 69.2 is:
9 December 2004

The applicant is hereby **invited to reply** to this opinion.

When? See the **Reply Due** date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the **Final Date** by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established.
If no response is filed by 1 month before the Final Date, the international preliminary examination report will be established on the basis of this opinion.
 Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least **3 months before the Final Date** by which the international preliminary examination report must be established.

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3.
 For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
 For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.
 For an informal communication with the examiner, see Rule 66.6.

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WRITTEN OPINION

International application No.

PCT/AU2003/000998

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed.
- ☒ the description, pages 1-2, 4-19, as originally filed,
pages 3, filed with the demand,
pages , received on with the letter of
- ☒ the claims, pages 20-22, as originally filed,
pages , as amended under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☒ the drawings, pages 1/9-9/9, as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-20, 22-24	YES
	Claims 21, 25	NO
Inventive step (IS)	Claims	YES
	Claims 1-25	NO
Industrial applicability (IA)	Claims 1-25	YES
	Claims	NO

2. Citations and explanations

Citations

This opinion has considered the following documents cited in the International Search Report:

D1: WO 2002/040034 A1

D2: WO 2002/040033 A1

D3: WO 2003/011303 A1

D4: WO 2003/049774 A1

D3-D4 were published prior to the international filing date but later than the claimed priority date but which would otherwise be considered to be of particular relevance. These documents will not be commented on in this report but may be considered relevant during national phase examination. See Box VI for further information.

D1 discloses compositions comprising phosphate derivatives of hydroxylated active's and compositions comprising complexes of one or more complexes of a phosphate derivatives of hydroxylated active's (eg complexes of tocopherol phosphate, retinol or ascorbic acid (See page 10 paragraph 2)). This document further discloses the use of said compounds as active's in therapeutic formulations and their use to enhance skin penetration. See example 25 page 31-34, claims.

D2 discloses compositions comprising phosphate derivative of electron transfer agents (eg tocopherol phosphate, retinol or ascorbic acid (see page 4 line 28- page 4 line 2)) and complexes of one or more complexes of a phosphate derivative of electron transfer agents (eg tocopherol phosphate) (see pages 7-9, example 2). This document further discloses the use of said compounds as active's in therapeutic formulations and their enhanced absorption properties, see claims, page 5 paragraph 3 - page 6 paragraph 5, table 1 page 9.

Novelty and Inventive Step

Claims 1-20, 23 encompass the use of one or more complexes of a phosphate derivative of a lipophilic compound (such as tocopherol phosphate) to improve the efficacy and/or transdermal transport of topically administered pharmaceutical's, ie the use of the said complexes as carriers.

Continued in Supplementary Box I

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VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
D3: P,X WO 2003/011303 A	13 February 2003	26 July 2002	27 July 2001
D4: P,X.WO 2003/049774 A	19 June 2003	13 December 2002	13 December 2001

D3 discloses topical compositions comprising one or more complexes of one or more phosphate derivatives of one or more electron transfer agents and their use to treat skin conditions (see claims).

D4 discloses topical formulations comprising complexes of one or more phosphate derivatives or one or more hydroxy compounds and their use of as carriers (see example 2, claim 9).

With regard to the document(s) listed in Box VI under "certain documents cited", these are documents published prior to the international filing date but later than the priority date claimed but which would otherwise be considered to be of particular relevance.

Under the PCT, novelty is considered only in respect of documents published before the priority date. The relevance of a document published after the priority date is dependent upon national law. Such documents are excluded from consideration in preliminary examination, under the PCT Guidelines but have been included here for information.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The invention defined in claim 24-25 is not supported by description. The inventive concept appears to be the use of **complexes** of phosphate derivatives in topical formulations to improve transdermal transport, for example see page 4 paragraph 5 of the instant application, however as currently drafted the claims are not limited to this feature.

Supplemental Box I

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of V

Claims 21 encompass compositions of one or more complexes of a phosphate derivative of a lipophilic compound (such as tocopherol phosphate), which merely have to be suitable as a carrier.

Claim 22 encompass compositions comprising a pharmaceutical agent and one or more complexes of a phosphate derivative of a lipophilic compound (such as tocopherol phosphate).

Claim 24 encompass the use of one or more phosphate derivatives of a lipophilic compounds (such as tocopherol phosphate) to improve the efficacy and/or transdermal transport of topically administered pharmaceutical's, ie the use of the said compounds as carriers.

Claim 25 encompass compositions of one or more phosphate derivatives of a lipophilic compounds (such as tocopherol phosphate), which merely have to be suitable as a carrier.

The invention defined in claims 21, 25 are not novel and do not involve an inventive step in light of D1-D2. These documents disclose compositions of one or more phosphate derivatives of a lipophilic compounds and compositions comprising one or more complexes of a phosphate derivative of a lipophilic compound. It is noted that the term "for use" (claim 21, 25) means the composition merely has to be suitable as a carrier and not limited to **when used**. Therefore the claims are to compositions of the said **complexes/compounds per se**. For this reason the invention defined in claims 21, 25 are not novel and do not involve an inventive step.

The invention defined in claims 1-20, 22-24 do not involve an inventive step in light of D1-D2. The difference between either of these citations and the instant application is that the citation **teaches** that compositions comprising one or more phosphate derivatives of a lipophilic compounds and compositions comprising one or more complexes of a phosphate derivative of a lipophilic compound **have enhanced penetrations properties** whereas the application utilises compositions of one or more phosphate derivatives of a lipophilic compounds or compositions comprising one or more complexes of a phosphate derivative of a lipophilic compound **as carriers due to the enhanced penetration properties**. It is well known that compounds with enhanced penetration properties are suitable for use as carriers in topical formulations. Therefore a person skilled in the art would be directly led to use these complexes/compounds as carriers to improve transdermal delivery upon reading either of these citations. For this reason a person skilled in the art would directly and without difficulty by routine steps, arrive at a solution which is the same as the claimed solution, and therefore claims 1-20, 22-24 lack an inventive step.

Industrial Applicability

All claims are considered to be Industrial Applicable.